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Display Date 3-7-00
Publication Date 3-8-00
Certifier

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 97P–0044]

New Drugs for Human Use; Clarification of Requirements for Patent Holder Notification; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of its proposed rule published in the **Federal Register** on March 6, 1998 (63 FR 11174). The document proposed to amend FDA's regulations on notice of certification of invalidity or noninfringement of a patent to provide additional methods for new drug and abbreviated new drug applicants to provide notice to patent owners and new drug application (NDA) holders, without removing the existing means. FDA is withdrawing this proposal based on comments regarding the inability of large corporations to track receipt of deliveries by means other than certified mail, return receipt requested.

DATES: The proposed rule is withdrawn [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 6, 1998 (63 FR 11174), FDA proposed to permit new drug and abbreviated new drug applicants to provide notice of certification of invalidity or

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noninfringement of a patent to patent owners and NDA holders by overnight delivery service, facsimile, and electronic mail, in addition to U.S. Postal Service (USPS) registered or certified mail, return receipt requested, or another method approved in advance by the agency. Sections 314.52(c) and 314.95(c) (21 CFR 314.52(c) and 314.95(c)) set forth the content requirements of the notice of certification. Under §§ 314.52(e) and 314.95(e), applicants must amend their applications to document receipt of the notice of certification by each person provided the notice. Applicants must include a copy of the return receipt or other similar evidence of the date the notification was received. FDA accepts as adequate documentation of the date of receipt a return receipt or a letter acknowledging receipt by the person provided the notice. Under §§ 314.52(e) and 314.95(e), applicants may rely on another form of documentation only if FDA has agreed to such documentation in advance. FDA reminds those providing notice of certification to application holders that if an application holder does not reside or maintain a place of business within the United States, notice must be sent to the application holder's U.S. attorney, agent, or other authorized official (§§ 314.52(a)(2) and 314.95(a)(2)). FDA also notes that the term ''registered or certified mail'' as used in §§ 314.52(a) and 314.95(a) means USPS registered or certified mail, and not equivalent delivery via foreign mail. Since the actual form of international registered or certified mail and receipt may vary from country to country, use of international mail could put a substantial burden on innovator companies to be alert to multiple forms of notice. Therefore, applicants must use USPS mail. Delivery by USPS mail should not be burdensome since applicants are required to have a U.S. agent.

II. Comments on the Proposed Rule

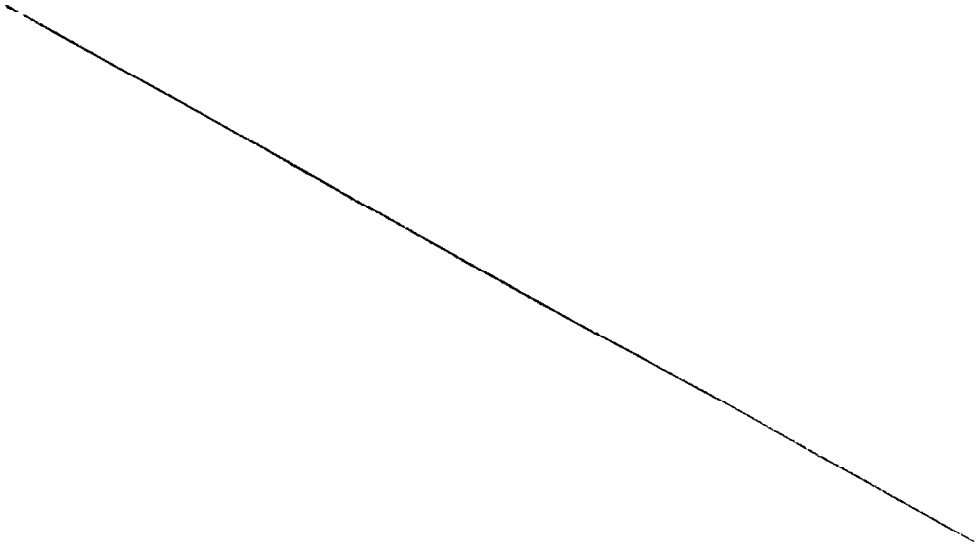
FDA received three comments on the proposed rule. The comments were from two large pharmaceutical companies and from the Pharmaceutical Research and Manufacturers Association. All of the comments stated that electronic methods of delivery, including facsimile and electronic mail, are too unreliable at this stage to be used to deliver notification.

One of the comments supported use of overnight and messenger delivery services. One comment stated that overnight delivery service would be acceptable only if the person receiving the notice signed a form verifying receipt of the notice. The other comment stated that overnight delivery services are not acceptable because deliveries are made in bulk, accompanied by a manifest that does not guarantee that each item listed is in fact in the bulk package and that individual items are not signed for.

All of the comments stated that the present system is workable.

III. Withdrawal of the Proposed Rule

After careful consideration of these comments, FDA has concluded that the current system, which requires only that an applicant send notice by USPS registered or certified mail, return receipt requested, is not overly burdensome. This requirement is intended to provide maximum assurance that the notice will be received by the patent holder and the NDA holder, and that such receipt will be documented adequately. In addition, FDA has concluded that adding new methods of notification presents complications in ensuring that notification is received by sponsors. Accordingly, FDA is withdrawing its proposed rule to permit new drug and abbreviated new drug applicants to provide notice of certification of invalidity or noninfringement of a patent to patent



owners and NDA holders by overnight delivery service, facsimile, and electronic mail, in addition to USPS registered or certified mail, return receipt requested, or another method approved in advance by the agency.

Dated: 2/29/00
February 29, 2000

Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F